

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 12-16, 18-23 and 25-30 are pending after entry of the amendments set forth herein.

Claims 1-11, 17 and 24 are canceled in view of the restriction requirement and the subject matter of these claims being directed to non-elected subject matter. Cancellation of these claims is without prejudice to renewal, without acquiescing to any rejection that may have been applied to the claims, and without intent to abandon any subject matter encompassed in the claims.

Claims 12, 19 and 25 are amended. Amendments to the claims are solely to provide that the subject matter of the claims are directed to the elected subject matter, and to avoid duplicity of the claims.

Support for the amendments to the claims is found in the specification at, for example, paragraphs 66 and 175.

Claims 28-30 are added. Support for new claims 28-29 is found in the specification and in original claims 12-25 as filed. Support for new claim 30 is found in the specification at, for example, paragraphs 66 and 175.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

Restriction Requirement

The Office Action set out a Restriction Requirement as follows:

Group I: Claims 1-26, drawn to an in vivo method of delivering insulin to the bloodstream of a mammalian subject, the method comprising: administering a formulation to a pancreatic cell of a mammalian subject,

the formulation comprising a nucleic acid encoding an islet transcription factor; and

Group II: Claims 12-27, drawn to a method for delivering insulin to the bloodstream of a mammalian subject, the method comprising: introducing an islet cell produced by the method of claim 25 into a pancreas of a mammalian subject.

The Office Action further required election of a species as follows:

If Group I is elected: Election of an islet transcription factor set forth from claims 2, 3, 5, 9, 10, 13, 14, 16, 21-23 is required. The Office Action notes that, currently claims 1, 12 and 19 are generic.

If Group II is elected: Election of an islet transcription factor set forth from claims 13, 14, 16, 21-23 is required. The Office Action notes that, currently claims 12 and 19 are generic.

If a generic claim is allowed, then the non-elected species within the elected group will be considered.

In response, applicants hereby elect to prosecute the claims of Group II, and elect the species of claim 13, which is the transcription factor Ngn3. Election is without traverse to the extent that applicants understand that the restriction requirement has restricted the claims according to methods of *in vivo* therapy (Group I), and methods involving *in vitro* production of islet cells and *ex vivo* therapy (Group II). If this understanding is incorrect, applicants hereby reserve the right to traverse the restriction requirement on the grounds that claims directed to *in vitro* production of islet cells and claims directed to use of such cells (as in *ex vivo* therapy) can be readily examined together and without undue burden on the Office.

Applicants have canceled the non-elected claims of Group I without prejudice, and have amended the claims of Group II without prejudice so as to direct these claims to the elected subject matter.

Conclusion

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCSF-129CIP.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1-11, 17 and 24 are cancelled without prejudice.

Add new claims 28-30.

12. **(Amended)** A method for producing an islet cells in vitro ~~in a mammalian subject,~~
the method comprising:

introducing a nucleic acid molecule into a ~~pancreatic~~ precursor cell in vitro ~~of a~~
~~mammalian subject,~~ the nucleic acid molecule encoding an islet transcription factor, said
introducing being in an amount sufficient for production of the islet transcription factor and
production of islet cells ~~in the pancreas of the subject.~~

19. **(Amended)** A method for producing a mammalian islet cell in vitro , the method
comprising the steps of:

introducing into a mammalian cell in vitro a nucleic acid molecule encoding an islet
transcription factor, said introducing providing for expression of the islet transcription factor in
the mammalian cell and production of the islet cell phenotype in the mammalian cell.

25. **(Amended)** A method for producing a mammalian islet cell in vitro , the method
comprising the steps of:

introducing into a mammalian pancreatic cell in vitro a nucleic acid molecule encoding
neurogenin3 (Ngn3), said introducing providing for expression of Ngn3 in the cell and
production of the islet cell phenotype in the cell.